EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC, *Plaintiff,* v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant.*	Case No. 1:22-cv-00397-JMC

PLAINTIFF'S RESPONSE TO DEFENDANT'S SUR-REPLY

Plaintiff Vein & Wellness Group's (VWG) responds to the Secretary's latest paper.

Initially, the Secretary asserts that unappealed ALJ decisions are merely "interim", "informal", and are not "final." *See* Dkt. #32-1 at 1-2, 4. However, the Secretary never says how an unappealed ALJ decision is not final. Pursuant to the Secretary's own regulations, ALJ decisions must be appealed within 60 days or they are binding on the parties. *See* Dkt. #24 at 18 (*citing* 42. C.F.R. § 405.1048(a); 405.1110(a)). Here, the Secretary did not appeal any of the prior ALJ' decisions on which collateral estoppel is based and, therefore, they are "binding" on the parties and final. Pursuant to the RESTATEMENT (SECOND) OF JUDGMENTS, § 13 (1980), a decision is "final" if it is "sufficiently firm to be accorded conclusive effect." Factors to consider in making this determination include: 1) whether the decision was avowedly tentative; 2) the parties were fully heard; 3) the court supported its decision with a reasoned opinion; and 4) the decision was appealed or capable of being appealed. *Id*. at Comment (g). In the present case, the prior decisions were not avowedly tentative, the parties were fully heard (even if the Secretary chose not to

appeal); the decisions were supported by reasoned opinions; and the decisions were capable of being appealed. Thus, in addition to the Secretary's own regulations providing that the decisions are binding and therefore "final", simply applying the test of the RESTATEMENT, the decisions are "final."

In the sur-reply, again without disclosing the fact, the Secretary relies on the vacated *Prosser* decision to contend otherwise. *See* Dkt. #32 at 2. Putting aside the impropriety of relying on vacated decisions without disclosing the fact, the Secretary's contention that decisions are not "final" unless deemed "precedential" by the Secretary does not withstand even a moment's scrutiny. First, of course, "precedential" and "final" are two distinct legal concepts and decision may be "final" while not being "precedential" (at least as to entities not party to the case). Indeed, VWG notes that the Fourth Circuit itself has long drawn such a distinction. Prior to the amendments to FED.R.APP. 32.1, unpublished (and, therefore, non-precedential decisions) could still be cited "for the purpose of establishing res judicata, estoppel, or the law of the case." *See* FOURTH CIRCUIT, RULE OF APPELLATE PROCEDURE 32.1. Thus, of course, "precedential" and "final" are two different things. Moreover, VWG notes that the Secretary has never designated a decision "precedential." Thus, the Secretary asserts that hundreds of thousands of cases have been disposed of without a single "final" decision and, of course, that is preposterous. The Secretary cannot avoid the application of collateral estoppel merely by contending that he has never issued a "final" decision.

The prior ALJ decisions are "binding" and therefore "final" and the Secretary does not show anything to the contrary. No possible further process with regard these decisions is identified or anyway that the decisions could be anything other than conclusive as to the matters decided. The decisions are "final."

Next, the Secretary asserts that the MAC's ability to consider new issues of which the insured/provider is not unfettered because it is limited by what is set forth in CMS' exceptions. *See* Dkt. #32-1 at 2. However, as argued by the Secretary, because CMS itself is not limited, neither is the MAC. That is, CMS can choose to appeal on any issue of which the insured/provider has no notice (as happened in this case) and, the Secretary contends, the MAC can take the matter up. Simultaneously, the insured/provider would be precluded from offering evidence to rebut the newly raised issue. *See* 42 U.S.C. § 1395ff(b)(3).

With regard to notice to whether VWG had notice, the Secretary does not dispute that there are 65 different ways that an item could be considered not "medically reasonable and necessary" and that VWG was accorded notice of only two of these (*i.e.*, alleged wrong billing code and LCDs). *See* Dkt. #32-1 at 2-3. Instead, the Secretary asserts that VWG bore the burden of disproving 63 bases on which the claims at issue were not rejected. Clearly, that is not notice that these issues were disputed and that approach would be totally inconsistent with both the limitation on submission of evidence after the QIC stage and the requirement that both redetermination and QIC decisions be detailed in order to guide appeals to ALJs.[1] A construction of the statutes/regulations which renders them superfluous/irrational is highly disfavored.

[1] Indeed, consistent with the statutory scheme, the time for notice of issues is at the redetermination stage. Pursuant to 42 U.S.C. § 1395ff(a)(5), a redetermination decision must be supported by a detailed decision setting forth the bases for the decision. Armed with that information, the insured/supplier can seek reconsideration and submit any evidence needed to rebut the conclusion on redetermination. The QIC then makes its decision based on reviewing the determinations below and any additional evidence submitted. *See* 42 C.F.R. § 405.968 ("The QIC reviews the findings on which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own."). Thus, the QIC decision can only be a subset of the issues of which the insured/provider had notice at the redetermination stage, otherwise the insureds/providers would not know which evidence to submit before they are barred from offering it after the QIC decision.

Next, the Secretary asserts that the sheer existence of the Medicare appeal process itself followed by judicial review means that Congress intended that collateral estoppel not apply. *See* Dkt. #32-1 at 4 ("Since Congress explicitly provided formal judicial review of Medicare claims determinations in federal court, the informal administrative review process set forth in the Medicare statue was never intended to bind the Secretary."). Respectfully, VWG does not know what the Secretary means by "formal judicial review" and "informal administrative review." Those are not phrases that appear in the statute or regulations and appear to be coined for this litigation. Rather than "formal" or "informal", there are just the requirements/procedures set forth by Congress in the statutes.

Simply applying the standards set forth by the Supreme Court, the Secretary did not meet his burden of showing that statutes passed by Congress evidence Congress' intent to abrogate the common law. Nothing in the Medicare Act "speaks directly" to the issue of collateral estoppel (*U.S. v. Texas*, 507 U.S. 529, 535 (1993)) or is in anyway inconsistent with it (*BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994)). Thus, the Secretary did not carry his burden to overcome the presumption of collateral estoppel.

Judicial review is fully consistent with collateral estoppel as is a "complex" appeal process within the Department. Indeed, appeal processes within agencies followed by judicial review are common and do not preclude collateral estoppel. For example, in *B & B Hardware*, the Supreme Court considered the application of collateral estoppel based on proceedings before the U.S. Patent & Trademark Office. 575 U.S. 138 (2015). As set forth in the relevant statute, trademark applicants or challengers first proceed before an Examiner and, if they are dissatisfied with the decision, may appeal to the Trademark Trials and Appeals Board (TTAB). Then, if they are still dissatisfied, they may seek judicial review, where the review is *de novo*. Nevertheless, the

Supreme Court affirmed the application of collateral estoppel based on proceedings before the USPTO. *Id*. at 152 ("Ordinary preclusion law teaches that if a party to a court proceeding does not challenge an adverse decision, that decision can have precluded effect in other cases even if it would have been reviewed *de novo*.").

Indeed, there is a strong presumption of judicial review of agency action just as there is a presumption of the common law (including collateral estoppel). *See, e.g., Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm'n*, 528 F.3d 310, 316 (4th Cir. 2008) (*citing Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986)). Thus, the idea that judicial review of an agency process is inconsistent with collateral estoppel simply flies in the face the presumptions and all the cases from the Supreme Court (*B & B Hardware*, *Astoria*, *Utah Construction*, etc.). Again, the Secretary did not sustain his burden to overcome the presumption of collateral estoppel.

Next, the Secretary offers that because he contends that the MOCA procedure is not "medically reasonable and necessary" coverage is precluded by the Appropriations Clause and that "collateral estoppel cannot be used to overcome the Medicare statute's prohibition on payment." *See* Dkt. #32-1 at 4-5. However, whether the MOCA procedure is "medically reasonable and necessary" is the very thing decided in the prior cases. Merely pretending that collateral estoppel does not apply/exist is not a basis for creating new bases for denial. In addition, the Secretary's argument has a certain circular quality.

Finally, the Secretary closes with the charge that it did not concede various things. *See* Dkt. #32-1 at 5. This Court can review the papers and decide whether the Secretary's most recent claim withstands scrutiny.

Dated: August 26, 2022

Respectfully submitted,

/s/Daniel Z. Herbst

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CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2022, a true and correct copy of the Plaintiff's Reply to Defendant's Surreply was filed via the Court's CM/ECF system and served upon all attorneys of record.

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